

[REDACTED]

Particularly when viewed in the context of the advances in the mAb therapy field in general, the attributes and strengths of mAbs are particularly well-suited to the demands of prostate cancer therapy:

1. mAbs can specifically localize to disseminated tumor sites at levels orders of magnitude higher than normal tissues.
 2. Therapeutic efficacy has been proven in tumor types (e.g., colon cancer and NHL) where the clinical setting resembles prostate cancer.
 3. mAbs have a number of potential mechanisms of anti-tumor activity including:
 - a. the relative radiosensitivity of PCa provides one potential class of cytotoxic agents to specifically deliver to tumor sites by way of mAb.
 - b. mAbs can trigger the host's own immune response to tumor.
 4. Prostate cancer metastases are small-volume sites (typically measured in microns or mm) ideal for radioisotope or immunotherapy.
 5. The availability of established parameters such as PSA and pathological features (e.g., stage, Gleason score, seminal vesicle invasion, positive margins, nodal disease, etc.), provide appropriate indications for adjuvant mAb therapy where such therapy is likely to be most beneficial.
 6. Last, but not least, is the fact that mAbs are non-toxic.
- [REDACTED]
- [REDACTED]

We believe that we are well on the way to prove that these advantages are more than just theoretical. We have recently completed our mAb Prost 30 biodistribution study in 15 patients with prostate cancer. Doses ranged from 1.0 to 20.0 mg of mAb. Fourteen of the 15 patients had their prostates *in situ* and were evaluable for localization of Prost 30. In all 14 of these cases, including two with prior radiation therapy, the prostate was successfully imaged. In two cases, patients had known sites of metastatic disease imaged on conventional CT scans: regional lymph nodes (both patients) and liver (1 patient). In these cases, these sites also were successfully imaged with Prost 30. In four cases, after resecting the prostate one week after mAb administration, the prostate specimens were scanned alongside specimens of blood drawn at the time of the resection (see appended representative figure). These studies confirmed specific uptake in the prostate at substantially higher levels than in the blood, and this uptake persists for more than one week. No patient on the trial had any side effects.

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ement. Furthermore, the cytotoxicity of these materials was

synergistic

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